

What is claimed is:

- 1 1. A computer implemented method of processing an electrocardiogram (ECG), comprising  
2 the steps of:
  - 3 receiving digital parameter data for a clinical study, said digital parameter data  
4 representing demographic data to be collected for ECGs associated with said clinical study and  
5 rules associated with said clinical study; and
  - 6 automatically generating a query if a problem is identified with said demographic data  
7 based upon said digital parameter data
- 1 2. The method of claim 1,
  - 2 wherein respective demographic data are identified as requiring either internal query  
3 resolution or external query resolution,
  - 4 wherein said digital parameter data include query resolution contact information,
  - 5 said automatically generating step further comprising the step of generating a query for  
6 an external contact in accordance with said query resolution contact information if said problem  
7 is associated with demographic data identified as requiring external query resolution.
- 1 3. The method of claim 2, further comprising notifying an internal contact of said problem  
2 if said problem is associated with demographic data identified as requiring internal query  
3 resolution.

1 4. The method of claim 2, wherein said query resolution contact information includes an  
2 identification of a party to be contacted and a contact method.

1 5. The method of claim 1, wherein said step of automatically generating said query includes  
2 the step of identifying whether demographic data are missing, said demographic data violate a  
3 rule associated with said clinical study, said demographic data are inconsistent with demographic  
4 data evinced by digital demographic data received for a second ECG associated with said clinical  
5 study, or a combination thereof.

1 6. A computer implemented method of processing an electrocardiogram (ECG), comprising  
2 the steps of:

3 receiving digital ECG data for a plurality of ECGs for a plurality of patients within a  
4 clinical study, said digital ECG data evincing a plurality of heartbeats detected during said  
5 plurality of ECGs;

6 providing interval duration data for said ECGs to at least one evaluating physician on a  
7 display, said interval duration data developed from digital interval duration data representing  
8 time durations of measured intervals associated with heartbeats from said plurality of heartbeats;

9 receiving digital evaluation data representing a medical evaluation by said at least one  
10 evaluating physician of respective ECGs from said plurality of ECGs; and

11 automatically identifying at least one ECG from said plurality of ECGs for quality review  
12 based on quality review rules.

1 7. The method of claim 6, further comprising displaying respective annotated ECG images  
2 to said evaluating physician for ECGs to be evaluated by said evaluating physician.

1     8.     The method of claim 6, further comprising the steps of;  
2             receiving digital parameter data for said clinical study, said digital parameter data  
3     representing said quality review rules,  
4             said automatically identifying step including the step of identifying said at least one ECG  
5     based at least in part on said received digital evaluation data or said digital interval duration data,  
6     or a combination thereof.

1     9.     A computer implemented method of processing an electrocardiogram (ECG), comprising  
2     the steps of:

3             receiving digital ECG data for a plurality of ECGs for a plurality of patients within a  
4     clinical study, said digital ECG data evincing a plurality of heartbeats detected during said  
5     plurality of ECGs;

6             providing interval duration data for said ECGs to at least one evaluating physician on a  
7     display, said interval duration data developed from digital interval duration data representing  
8     time durations of measured intervals associated with heartbeats from said plurality of heartbeats;

9             receiving digital evaluation data representing a medical evaluation by said at least one  
10    evaluating physician of respective ECGs from said plurality of ECGs;

11            automatically generating a report for at least one ECG from said plurality of ECGs, said  
12    report including evaluation data developed from said digital evaluation data associated with said  
13    at least one ECG from said plurality of ECGs; and

14            automatically providing said report to a party identified by digital reporting criteria for  
15    said clinical study and in a manner identified by said digital reporting criteria.

1 10. A computer implemented method of processing an electrocardiogram (ECG), comprising  
2 the steps of:

3 receiving digital ECG data for a plurality of ECGs for a plurality of patients within a  
4 clinical study, said digital ECG data evincing a plurality of heartbeats detected during said  
5 ECGs;

6 receiving digital interval duration data, said digital interval duration data representing  
7 time durations of measured interval associated with heartbeats from said plurality of heartbeats;  
8 and

9 providing said digital ECG data and digital interval duration data to a regulatory agency  
10 processor through a computer network from a computer processor unit remote from said  
11 regulatory agency processor.

1 11. An electrocardiogram (ECG) processing system, comprising:

2 means for receiving digital parameter data for a clinical study, said digital parameter data  
3 representing demographic data to be collected for ECGs associated with said clinical study and  
4 rules associated with said clinical study; and

5 means for automatically generating a query if a problem is identified with said  
6 demographic data based upon said digital parameter data.

1 12. The system of claim 11,

2 wherein respective demographic data are identified as requiring either internal query  
3 resolution or external query resolution,

4 wherein said digital parameter data include query resolution contact information,

5           said automatically generating means further comprises means for generating a query for  
6   an external contact in accordance with said query resolution contact information if said problem  
7   is associated with demographic data identified as requiring external query resolution.

1   13.    The system of claim 12, further comprising means for notifying an internal contact of  
2   said problem if said problem is associated with demographic data identified as requiring internal  
3   query resolution.

1   14.    The system of claim 12, wherein said query resolution contact information includes an  
2   identification of a party to be contacted and a contact method.

1   15.    The system of claim 11, wherein said automatically generating said query means includes  
2   means for identifying whether demographic data are missing, said demographic data violate a  
3   rule associated with said clinical study, said demographic data are inconsistent with demographic  
4   data evinced by digital demographic data received for a second ECG associated with said clinical  
5   study, or a combination thereof.

1   16.    An electrocardiogram (ECG) processing system, comprising:

2           means for receiving digital ECG data for a plurality of ECGs for a plurality of patients  
3   within a clinical study from a receiving station coupled to at least one remote electrocardiogram  
4   machine, said digital ECG data evincing a plurality of heartbeats detected during said plurality of  
5   ECGs;

6           means for providing interval duration data for said ECGs to at least one evaluating  
7   physician on a display, said interval duration data developed from digital interval duration data

8 representing time durations of measured intervals associated with heartbeats from said plurality  
9 of heartbeats;

10 means for receiving digital evaluation data representing a medical evaluation by said at  
11 least one evaluating physician of respective ECGs from said plurality of ECGs; and

12 automatically identifying at least one ECG from said plurality of ECGs for quality review  
13 based on quality review rules.

1 17. The system of claim 16, further comprising means for displaying on a monitor respective  
2 annotated ECG images to said evaluating physician for ECGs to be evaluated by said evaluating  
3 physician.

1 18. The system of claim 16, further comprising:

2 means for receiving digital parameter data for said clinical study, said digital parameter  
3 data representing said quality review rules,

4 said automatically identifying means including means for identifying said at least one  
5 ECG based at least in part on said received digital evaluation data or said digital interval duration  
6 data, or a combination thereof.

1 19. An electrocardiogram (ECG) processing system, comprising:

2 means for receiving digital ECG data for a plurality of ECGs for a plurality of patients  
3 within a clinical study from a receiving station coupled to at least one remote electrocardiogram  
4 machine, said digital ECG data evincing a plurality of heartbeats detected during said plurality of  
5 ECGs;

means for providing interval duration data for said ECGs to at least one evaluating physician on a display, said interval duration data developed from digital interval duration data representing time durations of measured intervals associated with heartbeats from said plurality of heartbeats;

means for receiving digital evaluation data representing a medical evaluation by said at least one evaluating physician of respective ECGs from said plurality of ECGs;

means for automatically generating a report for at least one ECG from said plurality of ECGs, said report including evaluation data developed from said digital evaluation data associated with said at least one ECG from said plurality of ECGs; and

means for automatically providing said report to a party identified by digital reporting criteria for said clinical study and in a manner identified by said digital reporting criteria.

20. An electrocardiogram (ECG) processing system, comprising:

means for receiving digital ECG data for a plurality of ECGs for a plurality of patients within a clinical study from a receiving station coupled to at least one remote electrocardiogram machine, said digital ECG data evincing a plurality of heartbeats detected during said ECGs;

means for receiving digital interval duration data, said digital interval duration data representing time durations of measured interval associated with heartbeats from said plurality of heartbeats; and

means for providing said digital ECG data and digital interval duration data to a regulatory agency processor through a computer network from a computer processor unit remote from said regulatory agency processor.